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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/716,489	11/20/2003	Gregory D. Plowman	034536-0181	8741

22428 7590 06/29/2005

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EXAMINER	
NASHED, NASHAAT T	
ART UNIT	**PAPER NUMBER**
1656	

DATE MAILED: 06/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/716,489	PLOWMAN ET AL.	
	Examiner	Art Unit	
	Nashaat T. Nashed, Ph. D.	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 November 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *14,15 and 33-37* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *14,15 and 33-37* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *11/20/03*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

The application has been amended as requested in the communication filed February 13, 2004. Accordingly, claims 1-13 and 16-32 have been canceled, and new claims 33-37 have been entered.

Claims 14, 15, and 33-36 are pending and under consideration.

The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code, see for example pages 45, lines 3 and 8, page 48, line 3, page 104, lines 7, 13, and 20, page 106, line 4, page 108, line 15, page 109, lines 10 and 11, page 110, line 12, page 113, line 6, page 114, lines 21, 24 and 27-29, and page 115, last line. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP 608.01.

The disclosure is objected to because of the following informalities:

(a) The assay described on page 121, lines 14-20 is an incomplete kinase assay and not a phosphatase activity. A protein phosphatase substrate is a phosphorylated protein. The only phosphate-containing reagent in the assay is a radiolabled ATP.

Appropriate correction is required.

Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 as follows:

An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification or in an application data sheet (37 CFR 1.78(a)(2) and (a)(5)). Specifically, applicants have not indicated the relationship between the instant application and copending application 09/866,987.

Priority Date for Claims 14, 15, and 33-37:

Provisional applications 60/246,974, filed November 13, 2000, and 60/208,291, filed May 30, 2000, as well as non-provisional application 09/866,987 do not contain the amino acid sequence of SEQ ID NO: 2. Since the sequences are only disclosed in the parent application, serial number 09/986,992 ('992), the priority date of the instant claims is the filing date of the '992 application, i. e., November 13, 2001.

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 14, 15, and 33-37 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific or substantial asserted utility or a well-established utility.

Applicants discloses the nucleic acid sequences (SEQ ID NO: 1) encoding the amino acid sequence of SEQ ID NO: 2. The polypeptide of SEQ ID NO: 2 is sought to be a protein phosphatase, which is a non-specific asserted utility. Applicant assigned the phosphatase utility to the polypeptide of SEQ ID NO: 2 based on a marginal sequence homology, at best, observed with a protein phosphatase 2C-like from *Arabidopsis thaliana* (Database: PIR, Accession number T50783 submitted July 2000 by Bevan *et al.*). The specification indicates that SEQ ID NO: 2 is 35% identical to the phosphatase 2C-like from *A. thaliana*, see page 114, first paragraph. In contrast, the examiners alignment of the two sequences produced 18.5% overall sequence homology, and 35.4% best local homology. So, it appears that polypeptide of SEQ ID NO: 2 is assumed to be a phosphatase based on a low sequence homology (18.5% or 35%!) observed to a polypeptide resembling a protein phosphatase, and has never been shown to be a phosphatase of any kind. Since sequence homology, if it exists, does not impart functional homology, one of ordinary skill in the art would doubt that the polypeptide of SEQ ID NO: 2 is a protein phosphatase of any kind. Even, if the examiner accepts the phosphatase as a credible asserted utility, which the examiner has to accept, phosphatase is a class of enzymes, which catalyzes the hydrolysis of many phosphorylated proteins. Each member of the class is expected to have different substrate having different structure and functions, and its action on that specific substrate is expected to have a specific biological consequences. The specification does not disclose a specific function of the polypeptide of SEQ ID NO: 2, its relationship to any disease, or any specific real world use. The specification does not disclose a single specific disease, which can be treated by a modulator of activity for the polypeptide of SEQ ID NO: 2. The wish list of diseases and disorders mentioned in the specification at pages 56-66 and claims 15 and 33-35 is noted, but there is no reason to believe that a modulator of the activity of the polypeptide would treat any of the mentioned diseases. It is highly unlikely that the phosphatase of SEQ ID NO: 2 would be involved with so many the diverse diseases and syndromes cited in the claims and specification. No teaching in the specification that any of the cited diseases or syndromes is due to an excess or lack of phosphotase activity, which may be treated with inhibitor or activator, respectively. The specification describes non-specific functions and uses for the protein, nucleic acid, modulator of activity of the alleged phosphatase activity, and antibodies. The utility of the nucleic acid is said to be used in a method to detect a human gene and to recombinantlly make the polypeptide of SEQ ID NO: 2 which neither the gene nor the polypeptide associated with any specific use or a disease. Also, the utility of a modulator is to treat just about any disease. It appears that the main utility of the polypeptide and nucleic acid is to carry out further research to identify the biological function and possible diseases associated with said function. Substantial utility defines a "real world" use. Utilities that require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use are not substantial utility. Thus, the claimed invention has no specific or substantial asserted utility.

Applicant is referred to the revised interim guidelines concerning compliance with utility requirement of 35 U.S.C. 101, published in the Official Gazette and also available at www.uspto.gov.

> The following is a quotation of the first paragraph of 35 U.S.C. 112:
> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 14, 15, and 33-37 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either asserted utility or a well-established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Claims 14, 15, and 33-37 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 14, 15, and 33-37 are directed to a method of treating any disease or syndrome or the wish list of diseases and syndrome in claims 15 and 33-35 using any modulator of the phosphatase activity of the polypeptide of SEQ ID NO: 2. The specification, however, only provides description of the polypeptide, the nucleic acid encoding said polypeptide, and a general method to obtain modulator for said polypeptide. It should be noted that, while inhibitors of phosphatases may be known in the prior art, activators of the phosphatase activity are not. The specification also fails to describe any specific compound, which may specifically inhibit or activate the phosphatase activity of the polypeptide either *in vivo* or *in vitro*. The specification fails to describe the biological role of the polypeptide in any disease or syndrome, or which of the mired diseases covered by claim 1 or the wish list of claims 15 and 33-35 requires an inhibitor or activators for an effective treatment. Given this lack of description of the claimed invention, Applicants have failed to sufficiently describe the claimed invention, in such full, clear, concise, and exact terms that a skilled artisan would recognize Applicants were in possession of the claimed invention.

> The following is a quotation of the second paragraph of 35 U.S.C. 112:
> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 14, 36, and 37 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The phrase "a method for treating a disease or disorder by administering to a patent in need of such a treatment" in claim 14 renders the claim indefinite because the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. For examination purposes only, it is assumed that the applicant mean treating any disease or syndrome known to mankind. Claims 36 and 37 are included in this rejection because they are dependent on the rejected claim and do not correct the deficiencies of the claim from which they depend.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
> (e) the invention was described in-
> (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or
> (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

Claims 14, 15, and 33-37 are rejected under 35 U.S.C. 102(e) as being anticipated by Au-Young *et al.* (IDS: WO 01/96546).

Au-Young *et al.* teach the human nucleic acid sequence of SEQ ID NO: 10 encoding the phosphatase of SEQ ID NO: 1 and named it PP1, see the sequence listing. The nucleic acid of SEQ ID NO: 10 taught by Au-Young *et al.* comprises the entire nucleic acid sequence of SEQ ID NO: 1 of the instant application. Also, the amino acid sequence of SEQ ID NO: 1 taught by Au-Young *et al.* is identical to the amino acid sequence of SEQ ID NO: 2 of the instant application. Also, Au-Young *et al.* teach the protein phosphatase activity of the polypeptide of SEQ ID NO: 1, see page 2, second paragraph. In addition, they teach a wish-list of disease and syndromes to treat with the said phosphatates or modulator of the phosphatase (claims 14, 15, and 33-37), see the last paragraph at page 39 through the end of the first paragraph at page 42. The amino and nucleic acid sequences of SEQ ID NO: 1 and 10, respectively, taught by Au-Young are fully disclosed in provisional application 60/212,447, filed June 16, 2000 which is a priority document for WO 01/96546.

Claims 14, 15, and 33-37 are rejected under 35 U.S.C. 102(e) as being anticipated by Xiao (IDS: WO 01/96571).

Xiao teaches the nucleic acid sequence of SEQ ID NO: 17 encoding the human phosphatase of SEQ ID NO: 19, see the sequence listing. The nucleic acid of SEQ ID NO: 17 taught by Xiao comprises substantially the entire nucleic acid sequence of SEQ ID NO: 1 of the instant application. The phosphatase of SEQ ID NO: 19 taught by Xiao is identical to the amino acid sequence of SEQ ID NO: 2. The priority documents of Xiao do not contain the amino acid sequence of SEQ ID NO: 2. Also, Xiao teaches the use of modulator of the phosphatase activity of the polypeptide of SEQ ID NO: 2 to treat wish list of disease, which include all diseases and syndrome listed in the claims (claims 14, 15, and 33-37), see page 58 through page 65.

Claims 14, 15, and 34-37 are rejected under 35 U.S.C. 102(e) as being anticipated by U. S. patent 6,653,102 ('102).

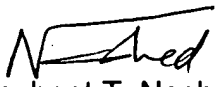
The '102 teaches the nucleic acid sequence of SEQ ID NO: 3 encoding the human phosphatase of SEQ ID NO: 4, see the sequence listing. The phosphatase of SEQ ID NO: 4 taught in '102 patent is identical to the amino acid sequence of SEQ ID NO: 2. The priority documents of the '102 contain the amino acid sequence of SEQ ID NO: 2 and its relationship to neurodegenerative diseases. Also, the '102 patent teaches that the polypeptide of SEQ ID NO: 4 is involve in Alzheimer's disease, and modulator of the phosphatase activity of the polypeptide of SEQ ID NO: 4 could be used to treat neurodegenerative diseases including Alzheimer's disease disease (claims 14, 15, and 34-37), see column 5, lines 6-20; column 32, line 25-64; and column 34 line 16 through column 35, line 11.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nashaat T. Nashed, Ph. D. whose telephone number is 571-272-0934. The examiner can normally be reached on MTTF.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy can be reached on 571-272-0928. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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Art Unit 1652